## **REMARKS**

This is in response to the action dated August 10, 2007.

## 1. Summary of Office Action

The Examiner noted Applicant's election.

Claim 15 was rejected under 35 U.S.C. 102(e) as anticipated by or, in the alternative under 35 U.S.C. 103(a) as obvious over Hoffman et al. '162 ("Hoffmann").

Claims 34, 39, 42 and 56 were rejected under 35 U.S.C. 103(a) as being obvious in view of Hoffman and Ishimaru et al. JP '076 ("Ishimaru").

Claims 14, 16, 19, 20, 22, 23, 27, 33, 35, 38, 43, 44, 55, 57 and 60 were rejected under 35 U.S.C. 103(a) as being obvious in view of Dreyfus '152 ("Dreyfus") and Ishimaru.

Claims 45, 47, and 48 were rejected under 35 U.S.C. 103(a) as being obvious in view of Dreyfus and Ishimaru and further, Morano '608 ("Morano").

Claims 30, 31, 46 and 53 were rejected under 35 U.S.C. 103(a) as being obvious in view of Dreyfus and Ishimaru and further, Yamamoto et al. JP '498.

Claims 70 and 71 were rejected under 35 U.S.C. 103(a) as being obvious in view of Dreyfus and Ishimaru and further, in view of Parkin '236 ("Parkin").

Claims 24-26, 49 and 50 were rejected under 35 U.S.C. 103(a) as being obvious in view of Dreyfus and Ishimaru and further, in view of Fort '733 ("Fort").

Claims 28, 29, 51 and 52 were rejected under 35 U.S.C. 103(a) as being obvious in view of Dreyfus and Ishimaru and further, in view of Fort and Dunn '766 ("Dunn").

## 2. Status of Claims

Claims 1-15, 17-20, 22-34, 36-39, 42-56, 58-69 and 71 are pending. Claims 14-16, 19, 20, 22-31, 33-35, 38, 39, 42-53, 55-57, 60, 70 and 71 were rejected.

The Examiner indicated that claim 21 would be allowable if rewritten into independent form including all of the limitations of the base claims and any intervening claims. Claim 21 was combined into the parent claim (Claim 19). Therefore, claim 19 should be allowed. The same limitation from claim 21 was entered into claims 30 and 71, and therefore, these claims should now also be allowable for the same reasons. The Examiner indicated that claims 1-13, 32 and 54 were allowed and confirmed that claims 40, 41 and 72 were canceled.

## 3. Response to Rejections

Claim 15 was rejected under 35 U.S.C. 102(e) as anticipated by or, in the alternative under 35 U.S.C. 103(a) as obvious over Hoffman et al. '162 ("Hoffmann"). Hoffman includes a solid nipple having ducts coated a portion of the length of the each duct with a hydrophobic material. (see Col. 9, lines 1-20) The current amendment overcomes the objection, by incorporating limitations from claim 1, which is allowed and claim 21, which was indicated as being allowable. Namely, claim 15 now recites a substantially solid nipple having a Shore A hardness of less than about 10 yielding a very soft solid nipple, including one or more ducts formed therethrough for conveying fluids through said nipple and having a flow restrictive feature presented by said very soft solid nipple which in use is capable of contraction along its radius. Because claim 15 recites allowable subject matter from claim 1 and claim 21, it should be in condition for allowance.

Claims 34, 39, 42 and 56 were rejected under 35 U.S.C. 103(a) as being obvious in view of Hoffman and Ishimaru et al. JP '076 ("Ishimaru").

All four of these claims require a substantially solid nipple made of a very low durometer material. Claims 34, 39 and 42 specify less than about 5 (Shore A) and claim 56 specifies a material much lower than 5 (Shore A) hardness (Shore OO of 20-45). None of the references teach or suggest alone or in combination (even if proper to combine) a substantially solid nipple with a

hardness of less than about 5 (or Shore OO of 20-45). In fact, both references teach a range higher than that claimed. Accordingly, there is no *prima facie* case of obviousness.

Hoffman shows only solid nipples that are "not hollow rubber shells" made of conventional materials. Conventional materials are significantly higher than the claimed range. Furthermore, Hoffman, while mentioning that the nipple may be made of one material, discussed a nipple having a core made of "more firm or rigid" material than "the nipple body material in order to better keep the fluid-delivery capillaries open when the baby bites on the nipple." (see Col. 10, lines 26-32) Hoffman teaches, therefore, that in order to keep the capillaries open in the solid nipple made of conventional material, it may be desirable or even necessary to have the core of the nipple made of material which is more firm or rigid than conventional nipple material.

In contrast to the nipple of Hoffman, Ishimaru shows only hollow rubber shell type nipples. Ishimaru discloses a preferred hollow nipple of "15 degrees," a preferred range of "10-30 degrees," and a broad range of 5-30 degrees (Shore A hardness). Ishimaru teaches that "hardness used less than 5 degrees *isn't used*.

Thus, Hoffman is used by the Examiner to show a solid nipple of conventional or harder material and Ishimaru is used to supply the deficiency of Hoffman in supplying a lower than conventional hardness material for the nipple. One important factor indicating lack of obviousness in this instance, is the lack of predictable results when combining elements of different structures. The Hoffman nipple is solid with capillaries and the Ishimaru nipple is hollow with a single, large duct. This is significantly different to the extent that a worker in the art would not likely be able to predict the results of lowering the hardness of the Hoffman nipple – especially when Hoffman explicitly mentions that it may be necessary to use a harder material than conventional to prevent flow problems through the nipple. In this instance, Hoffman teaches away from combination with any nipple of relatively low durometer material because Hoffman cautions against using a low hardness material by suggesting that a higher than conventional material might be necessary.

The Examiner notes that the present nipple is made of the soft material claimed "permitting the channel to pinch with sufficient pressure." Applicant notes that Hoffman cautions against using too soft a material, disclosing only conventional materials or material having a higher hardness than conventional, thus teaching away from use of a soft material. Furthermore this is not a requirement

of claims 34 and 56.

Claim 34 depends from claim 15, which claim now includes the limitations from claim 1. In particular, the claim requires "substantially solid nipple including one or more ducts formed therethrough for conveying fluids through said nipple, said nipple being radially compressible so as to prevent passage of fluids through said one or more ducts when so compressed" and "having a Shore A hardness of less than about 5 yielding a very soft solid nipple." This is distinguished from the prior art as the radially compressible limitation has already been allowed, and further by specifying a low durometer material having a range which the prior art teaches away from.

Claim 56 also depends from claim 15, which is patentably distinct from the references but additionally requires a durometer material significantly lower than any disclosed in the prior art including Ishimaru. For at least this reason, it should be allowed. Hoffman and Ishimaru fail to teach all of the claimed limitations, fail to provide the suggestion to combine or motivation regarding modification, and furthermore, teach away from the combination. Thus, claims 34, 39, 42 and 56 cannot be considered obvious in view of this rejection.

Claims 14, 19, 20, 22, 23, 27, 33, 38, 43, 44, 55, and 60 were rejected under 35 U.S.C. 103(a) as being obvious in view of Dreyfus '152 ("Dreyfus") and Ishimaru. Claims 16, 35, and 57 were canceled. Ishimaru is described above and should not be combined with Dreyfus for at least the reasons given above applied to Hoffman. Dreyfus shows a nipple with a solid tip, but a partially hollow construction. Dreyfus mentions that it is this partially hollow construction that permits the nursing nipple to mimic the human breast in function.

Dreyfus also discloses use of vulcanized India rubber, which has a hardness at least that of typical, conventional natural and synthetic elastomeric rubber materials. As shown above, because of the different structures of Dreyfus and Ishimaru there is no reasonable expectation that one could merely build the nipple of Dreyfus with a very low durometer material and expect that it would be successful in providing the benefits provided by the claims invention. Contrary to the Examiner's allegation that Dreyfus teaches a soft nipple, it is mentioned by Dreyfus that the construction of the nipple, being partially hollow, is responsible for its function. (see Col. 1, lines 53-55 and Col. 3, line 17)

Present claims 14, 19, 20, 22, 23, and 27 all specify a Shore A hardness of less than about 10. Claims 33, 35, 38, 43, and 44 all specify a Shore A hardness of less than about 5 and claims 55, 57 and 60 all specify a Shore 00 hardness of about 20 to about 45. There is no reasonable expectation, that one with ordinary skill in the art reading the prior art of Dreyfus and Ishimaru, would conclude that a solid nipple formed of these material harnesses would be successful. Therefore, claims 14, 19, 20, 22, 23, 27, 33, 38, 43, 44, 55 and 60 cannot be considered obvious in view of the combination, even if it were proper to do so.

Claims 45, 47, and 48 were rejected under 35 U.S.C. 103(a) as being obvious in view of Dreyfus and Ishimaru and further, Morano '608 ("Morano"). Claims 30, 31, 46 and 53 were rejected under 35 U.S.C. 103(a) as being obvious in view of Dreyfus and Ishimaru and further, Yamamoto et al. JP '498. Claims 70 and 71 were rejected under 35 U.S.C. 103(a) as being obvious in view of Dreyfus and Ishimaru and further, in view of Parkin '236 ("Parkin"). Claims 24-26, 49 and 50 were rejected under 35 U.S.C. 103(a) as being obvious in view of Dreyfus and Ishimaru and further, in view of Fort '733 ("Fort"). Claims 28, 29, 51 and 52 were rejected under 35 U.S.C. 103(a) as being obvious in view of Dreyfus and Ishimaru and further, in view of Fort and Dunn '766 ("Dunn").

All of these rejections require that one with ordinary skill in the art would recognize that the combination of a substantially solid nipple (which arguably Dreyfus is not) made of a conventional rubber material would function properly if made of a low durometer material of a range at or below that shown in Ishimaru, which is not of solid nipple construction. Because the art teaches that a solid nipple (see Dreyfus) is formed of conventional hardness material as opposed to hollow construction, and because the art suggests that a higher than conventional material might be needed (see Holloway) in a solid nipple there is no suggestion to combine solid nipples with low durometer hollow nipples and no motivation to modify a solid nipple to make it softer than the range taught in the hollow nipple reference. In fact, there is a clearly demonstrated teaching away of the prior art.

Since, Dreyfus and Ishimaru cannot render present claims 14, 19, 20, 22, 23, 24, 26, 27-31, 33, 38, 43-50, 51-53, 55, 60 and 71 obvious, and the remaining references do not supply the deficiencies of Dreyfus and Ishimaru, the claims should be allowed.

Reconsideration is requested of all the pending claims not previously allowed.

Respectfully submitted,

Date: November 29, 2007

Steven B. Courtright

Patent Agent

Reg. No. 40,966